UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

In Re: Levaquin Products Liability Litigation,	File No. 08-md-1943 (JRT/AJB)
	Minneapolis, Minnesota October 22, 2010 7:30 A.M.

BEFORE THE **HONORABLE JOHN R. TUNHEIM**
UNITED STATES DISTRICT COURT JUDGE
(MOTIONS HEARING)

APPEARANCES

For the Plaintiffs: **RONALD S. GOLDSER, ESQ.**
LEWIS J. SAUL, ESQ.

Cheryl Blume: **PHILIP CAMPBELL, ESQ.**

For the Defendants: **JOHN DAMES, ESQ.**
WILLIAM ESSIG, ESQ.
WILLIAM H. ROBINSON, JR., ESQ.
TRACY J. VAN STEENBURGH, ESQ.
JOHN WINTER, ESQ.

JOHN O'SHAUGHNESSY, ESQ.
(Johnson & Johnson in-house counsel)

Court Reporter: **KRISTINE MOUSSEAU, CRR-RPR**
1005 United States Courthouse
300 Fourth Street South
Minneapolis, Minnesota 55415
(612) 664-5106

Proceedings recorded by mechanical stenography; transcript produced by computer.

7:30 A.M.

(In open court.)

THE COURT: You may be seated. Good morning, everyone. This is multi district litigation number 08-1943, In Re: Levaquin Products Liability Litigation. Let's see. We're still turned up today. We will see how this works. I may have to try to turn -- we had a witness at the end of trial yesterday on video who was so, we could hardly hear him. So we had everything turned up, so that might be the problem. We'll adjust it.

Let's have counsel note appearances this morning, first for the plaintiffs.

MR. GOLDSER: Good morning, Your Honor. Ron Goldser for plaintiffs, and I have the pleasure of introducing Philip Campbell. Mr. Campbell is from Tampa, Florida. He has been retained by Ms. Blume to represent her personally on her charge of perjury.

THE COURT: Very well. Mr. Campbell, good morning. Mr. Saul.

MR. GOLDSER: And with your permission Mr. Campbell would like to address the Court as part of the argument.

THE COURT: Very well. For the defense?

MR. DAMES: John Dames, Your Honor.

THE COURT: Mr. Dames.

MS. VAN STEENBURGH: Tracy Van Steenburgh, Your Honor.

MR. ROBINSON: Bill Robinson, Your Honor.

MR. O'SHAUGHNESSEY: John O'Shaughnessey, Your Honor. Good morning.

MR. ESSIG: Bill Essig, Your Honor.

MR. WINTER: John Winter, Your Honor. Good morning.

THE COURT: Good morning to all of you. Okay. This is going to drive me crazy. I will just keep things away from me. Okay. Let's try it there.

Which one are we taking first this morning? We have three motions: The plaintiffs' motion to exclude expert Waymack, defendants' motion to exclude expert Blume, and then the conduct issue regarding Ms. Blume.

MR. GOLDSER: Mr. Dames and I agree that the Blume motions should go first. We thought it appropriate that Mr. Winter defend his charge of perjury as the first order of business this morning.

THE COURT: Okay. Mr. Dames?

MR. DAMES: I would phrase it slightly differently, Your Honor, but --

THE COURT: Okay. So there we go.

MR. WINTER: Good morning, Your Honor. May I proceed?

THE COURT: You may.

MR. WINTER: Thank you, Your Honor. Your Honor, you have a lot of paper relating to the two Blume motions, and what I would like to do is start with a reply to the response on the conduct motion, as we call it, and before I talk about the response and the explanations for why the statements were not perjurious, I would like to step back for a second.

Judge, you know this litigation is about an allegation relating to the comparative toxicity of Levaquin versus other fluoroquinolones. About 15 months ago, 14 months ago you held a hearing on a motion made by the plaintiffs, supported by an affidavit from Ms. Blume, that she needed to see our Floxin NDA and the adverse event data specifically in that in order to form her opinions.

Her affidavit said to you, I can't help the plaintiffs unless I see the Floxin adverse event data, and you granted that motion, and we went through significant expense to comply with that order. So when Ms. Blume submits her expert report, which doesn't mention anything about Floxin, and as you know from the cases that have been cited to you, experts fall into patterns.

They're going to do these PRR analysis, proportionate reporting ratio, and we'll talk about that, and they had been saying comparative toxicity, comparative

toxicity. And Ms. Blume and Mr. Altman have worked together in other cases, so we know what they generally do, and we have cited you the opinions where that analysis had been excluded.

So you go into a deposition and you say in words or substance, we didn't see that you did this analysis, and the answer was, that's right. We did not, and I'm going to use the word "we" a lot, Judge, because apparently one of the explanations here is that we, meaning the defendants, misunderstood when Ms. Blume said "we" that she had a meaning separate and apart from every other time she uses the word.

We were led to believe that this analysis had not been done, plain, pure and simple. We will show you the slides. That can't be denied that she said that analysis was not done. We then look at the analysis she gave us. You allowed us to take Mr. Altman's deposition, and we greatly appreciate that, because you will see Mr. Altman flat out says, Ms. Blume told me to do this. I did it. I gave it to her, and we did not give it to you.

So that presents a very difficult problem for you and for the defendants because this is not a discovery dispute. This is about someone who intentionally misled people at a deposition, and it's not about a tangential issue, Your Honor, and we're going to talk about this, what

the data they didn't produce means. This was their core issue, comparative toxicity.

And the notion that we're not prejudiced because they produced the data, that misses the point entirely, Your Honor. Someone has lied. They violated a fundamental rule that you must apply in your courtroom that it's not about seeing the data, which we have, and we'll talk about that.

Mr. Goldser was very, very good on October 1st. He provided data, and we're going to show you that transmittal because there is something very important in that transmittal, but the issue is fundamental, and it's not one you can have a meet and confer about.

I have some slides, Your Honor, which we're putting up here. Your Honor, you have a few copies if -- all right. Very quickly because I know we have some time issues here, this is Mr. Altman's deposition, Judge, and these are not trick questions.

You didn't compare Levaquin and Cipro, Levaquin to Ciprofloxacin?

Answer: Well, I couldn't do that with SCEPTRE.

And as Your Honor knows, SCEPTRE is our company internal database. AERs is the FDA database.

Well, if you couldn't do it with SCEPTRE because that only has Levaquin, but you did other comparisons?

Yes, I did.

They're not in Ms. Blume's report?

That's -- everyone agrees.

Which ones did you compare?

Floxin and Cipro.

So Ms. Blume at her deposition, we will see it, flat out said they didn't do that, and is there any question because I said, well, like whose idea was this? Maybe it was Mr. Altman's idea, and Ms. Blume said, no, which is a possibility.

It is undisputable that Ms. Blume told Mr. Altman to do this analysis, to run these two other medicines. It can't be disputed that it was provided to Ms. Blume. Your pretrial order number 5 expressly says, and we highlighted the two parts from paragraphs 8 and 9, and we will talk about their explanation from paragraph 4 in a second, received or reviewed.

There is no disputing that Ms. Blume received that. We now have the confirmation from the e-mail that she had received it, and she had it prior to signing her report on March 30th. She said she looked at it but discarded it.

So either, I mean, the "or" wouldn't change that. So you have someone who violated your pretrial order. The explanation in the response is that, well, paragraph 4 of

this same order says, communications with consultants, other lawyers are something that doesn't have to be reproduced.

I have not heard someone on the plaintiffs' side say we knew about this analysis, and we advised Ms. Blume that because Mr. Altman said this, that makes it a communication exempt from the disclosure requirements of your order.

If someone wants to get up and make that argument to you, they will make that argument to you, and we'll respond to it, but I have to respectfully suggest, Judge, because I do know how we respond to your orders, that is parsing your order in a way that it just -- you're the judge. It's your order.

If someone wants to say that's what they did, you'll address it, but that was not the explanation that was ever proffered until the conduct motion, and no one has said that that was the analysis they in fact did and that's why they didn't produce it.

The deposition notice was equally clear, and just, just to sort of put something in perspective, Judge, if Ms. Blume said at her deposition, yes, I had done this PRR analysis and I discarded it and I didn't put it in my list of documents that I reviewed in my report, we would have had a discussion at the deposition. We would have

then had a meet and confer, and something would have happened as a result of that, and we would not, I respectfully suggest to you, be here today.

So that, you know, this motion is a result of someone not telling the truth and then having to go to Mr. Altman's deposition to find out the truth. Just to remind Your Honor, we quoted Ms. Blume's July 2009 affidavit to you. In other words, I need the Floxin adverse event data. 15 months later, I looked at that last night, I think it's 15 months later she says, I didn't consider it. It's not relevant to my opinions.

Now, this is Mr. Altman and this proportionate reporting ratio analysis, and very simply, Judge, what that happens -- what you do is, you take the total number of reports, usually serious adverse event reports, and you say what are the tendon ruptures. And it's the tendon ruptures as a percentage of the total number of reports, it's a number, and then you say what's the same number for Cipro. So you're comparing these two types of numbers to see is there a trend.

And you'll see that that is an analysis that pharmacoepidemiologists do, and the rule is, if you're comparing two medicines and you'll see it, if the difference is more than two between them, it's something that requires you to take another step. There is a *Daubert*

motion part of this. We'll talk about, you know, is there another step.

So if it's more than two, you have to look at it. Now, this is the analysis that Mr. Altman provided to Ms. Blume, and the explanation is -- forget the communication position -- is that, A, she just forgot about it; B, we misunderstood her use of the word "we" and that she looked at it and discarded it because there was this other publicly available information that she wanted to use.

We're in 100 percent agreement about what the words mean here, PRR. It's not that someone misunderstood the type of report. There is no disputing that she had it in 2009 when she did her analysis, but she says that I didn't consider it.

Now, there is apparently a hiatus in when Ms. Blume does her report because there were several extensions here. So she goes from November. Puts it down. Comes back in February or March. Does Mr. Altman act independently? This is Ms. Blume. Mr. Altman would not do that unless we asked him to do that. He does not do any independent work.

You have it right there, Judge, a screen shot, and I think I have blowups of those, like eight and a half by eleven, but what you see there, Judge, this is verbatim

Mr. Goldser's e-mail to Mr. Robinson on October 1st. Please find all the materials in the AER database exactly in the form as I am advised that they were transmitted from Altman to Blume.

When you look at the screen shots, Judge, there are two sets of dates. One date is November 9, 2009, and all of that is the worldwide data for SCEPTRE and the worldwide data from the AERs database. The second column, Judge, and we gave you a little blowup on the side there, is all of the U. S. data, SCEPTRE and AERs.

That was transmitted, Judge, on March 23rd, 2010. So when you ask us -- she gave us a response. She considered it in November of 2009 and then discarded it. Judge, that statement also is not true. That statement in her affidavit according -- and Mr. Goldser is an honorable man. He provided that information to us.

It says in no uncertain terms, unequivocally, that in March of 2010, one week before she signed her report, she gets this AERs data. And if we go back a slide, Judge, Mr. Altman does not work independently. He does what I tell him to do.

So the notion that she discarded it in November, Judge, or somehow forgot about it, I mean, this is a difficult -- we understand this is a difficult decision for you, but this is a decision you have to make. This goes to

the integrity of the Court here. Serious accusation is made, and then someone's explanation just factually is not correct.

This is proportion reporting ratio. The lawyers, you know, sometimes we ask double negative, and we're not the clearest questioners, but because she has been deposed a lot, she knows. This is not what you did here? Correct. In other reports we had compared them where we have done this. They did not do that here.

Now, Judge, they did it twice, worldwide and U. S. That statement, Judge, can't be deemed to be true. That statement has to be found by you to be false. We did not do the AERs data in this case. Judge, you now have clear and unequivocal proof that they did it twice, worldwide and U. S., and I don't need to go back to the slide, where Mr. Altman only does it when Ms. Blume tells him to do it.

And we're going to look at that citizen petition like we didn't do because we had the citizen position, we are going to show you that, Judge. That explanation also doesn't hold water. This is sort of, we misunderstood -- the defendants misunderstood her word, use of the word "we." We did not independently run the AERs database.

Now, her response, apparently this "we" is her company, PDG. Now, I don't know how you square her

testimony that Mr. Altman does not act independently. He only does things when I tell him, to be parsing that word "we" the way she now is doing.

We don't have to have a perjury trial here where twelve people come in and decide if that explanation is such that she, you know, has guilt beyond a reasonable doubt. That's not what your inquiry is here, and that explanation, you know, I don't believe is worthy of belief. But the fact of the matter is, Judge, for the integrity of a civil case and the allowing of an expert the privilege to testify, I don't think it is.

It never -- and this is her explanation. It never entered my mind. If you look here, Judge, these are other examples of Ms. Blume talking about what she and Mr. Altman did to compare the tables that are in the report, and this is it: We did this. We did this. We did this.

Now, if I'm understanding, we take someone's deposition and for 20 answers, we're supposed to understand what the "we" means, meaning Mr. Altman and Ms. Blume, but in one particular question, we're supposed to have intuited that that was a different use of the word "we."

Here, Judge, this twofold, you know, and people get access to depositions, which is fair and legitimate, and so you know what someone would say if asked the same

question. She has testified that for this PRR to be relevant, it's got to be more than two, and she says now I didn't use it, and they think that I didn't use it because it doesn't help my opinion, but ah, now I think it strongly supports my opinion.

These are graphics, Judge, from her supplemental report, and if we have to give you better color copies, we will, but you have Levaquin, Floxin and Cipro, different lines here that Mr. Altman did, and this is from the U. S. patients, which is the March 23rd, 2010, which was attached to her report.

And you see the way that the lines are close together, Judge, up until 2007? Well, the PRR, you would have to have something being double in order for something to be a safety signal that you would have to think about.

So the reality is, Judge, and I think you can fairly conclude, this doesn't show that there is a safety signal when she did this comparative analysis. Yeah, if you look at 2008, Judge, which is the far right, after this MDL is created and you get every lawsuit turning into an adverse event report, that's -- you are going to get that change there. But they are all, sometimes they even intersect.

Judge, to switch to part of the *Daubert* argument at this point, the law is I think reasonably clear about

what the expert has to do, and an expert, we don't disagree that an expert can employ a consultant to help the expert, but the expert has to be able to stand up and say, this is the analysis, and I can defend it and explain it.

This goes to her -- Mr. Altman's SCEPTRE analysis, Judge, and they say, there are problems with these adverse events, and I think we cited to you 15 cases in either the initial *Daubert* motion or the reply where courts have excluded analysis based on adverse event reports.

And one of the reasons that happens, Judge, is that adverse event reports, you can't just look at numbers. You have to look at the quality of the data, and the quality of the data is inherently suspect just because of the nature of the data. So they say no, Dr. Blume, Ms. Blume looked at all the reports, and she placed appropriate weight on them.

If you look at what Mr. Altman said, he never sent her the underlying reports, so there is no weighting that she did. These reports have descriptions, and they have back and forth with doctors. She never looked at that. He expressly testified he didn't provide it. He said she did not evaluate his numbers, and it's pretty clear.

He did a counting exercise. He takes her SCEPTRE

database and says, every time there is a tendon rupture in a box, put it in a column, and that's -- he did that counting exercise, and we're not disputing that he counted right. It's what you do with that data that is the question, and every court says the counting exercise is not admissible because what you are counting is not reliable, the adverse event reports.

Ms. Blume has expressly testified that she can't validate, and it's there --

MR. GOLDSER: Excuse me, Your Honor. If I may interrupt, are we going to do both the *Daubert* motion and the perjury motion together?

THE COURT: Well, that was the plan. I have trial at nine o'clock. So can we focus a little more on the prejudice side of this?

MR. WINTER: Sure.

THE COURT: Let's turn to that. I'm wondering, I would like to have you address that issue.

MR. WINTER: Well, we can't say to you today, Judge, that we don't have the data. We do have the data. Judge, do we have the opportunity to meaningfully examine Ms. Blume about the data that she did not produce? Answer: Definitely not.

I mean, the way discovery works, she should have disclosed this prior to her deposition. It would have been

the subject of deposition questioning. We would have made a motion to you that says based on the *Meridia* case, based on *Baycol*, based on this case, proportionate reporting ratios are inadmissible for the following reasons, Ms. Blume agreed to this.

We also would have had the opportunity to say, Ms. Blume, isn't the rule of thumb two times the situation it creates something you need to do something on. She would have to presumably agree to her prior deposition sworn testimony, which is yes, because that is the rule.

Ms. Blume, does this show more than two for the U. S.?

No.

Ms. Blume, does this show more than two for the U. S. in 2004?

No.

Now, Judge, their case is, there is an increased risk of tendinopathy with Levaquin and that we missed a safety signal, we should have warned about something. Have we been prejudiced by not getting those admissions, which the evidence clearly indicates we should have gotten, by her not telling the truth about the data?

We could have made a summary judgment motion on the adequacy of warnings based on her admissions that would have to be given if she was going to testify under oath the

same way she did before looking at the data.

So, you know, I'm not suggesting how you would rule on a summary judgment motion, Judge, but we have been deprived of a very powerful evidentiary tool, and I would respectfully suggest to Your Honor that it is for that reason she lied.

You -- you have a set of rules on how discovery proceeds, and expert discovery is very important, and there is a schedule. It gets compressed. A lot is going on, and for us to be, to use a word, "sandbagged" the way we were clearly is prejudicial.

Now -- but, you know, we're all lawyers, and we know things have to be changed and adjusted, but it still is fundamentally unfair to have been confronted with what we were confronted with. And we believe there would be damning admissions that we would have obtained on -- again, Judge, this is not some side issue. This is the fulcrum of their case.

This is the reason they went to you a year and a half ago to say, order more discovery. Do we have the right now to go back to you and say, Judge, it was a Rule 37 violation for that affidavit to have been submitted. We spent, you know, X hundreds of thousands of dollars producing Floxin data pursuant to your order because Ms. Blume perjured herself? I mean, we could do that, but

again, Judge, that's not why we're actually here today.

But you have asked about prejudice, and this, what this witness did goes to the core of how these cases are proceeding. We have been very severely prejudiced by her misconduct. I don't think I can say more on the prejudice issue, Judge. I know we have time issues. Do you want me to continue?

THE COURT: That's fine. Let me hear from the other side.

MR. WINTER: Judge, just so, if I could just, I wanted to show you toward the end of the slides where she said it was because of the public citizen data.

THE COURT: Right.

MR. WINTER: That's the public citizen data, Judge. I mean, it is not even close to that proportionate reporting ratio analysis. It doesn't look anything like the tables in her report or in that AERs analysis. So to say that she said, well, I have this in lieu of the analysis that we showed you from Mr. Altman, Judge, just, that can't be correct.

Thank you, Your Honor.

THE COURT: Mr. Goldser?

MR. GOLDSER: Thank you, Your Honor. You also of course will hear from Mr. Campbell. I don't know whether to be sad or appalled at this motion. As you have seen for

several years, the relationship between the parties has been a good one. We have had our fights, but it's been a good relationship, and with this motion that Mr. Winter has made up, that has completely changed the landscape.

That makes me very sad, but I am appalled because this is a personal vendetta, not only of Mr. Winter but also of big pharma. They can't stand the fact that one of their own, somebody who has done good work for the industry for many years, will every once in a while stand up and say, you know what, big pharma, you're wrong. They can't abide that.

The attacks have gotten more vicious, more vitriolic from case to case to case, and this is the height, and it's time to put a stop to this. It's no more evident than Mr. Winter's continuing and ceaseless refusal to address a PhD recipient as Ms. Blume. Mr. Altman asked that he refer to her as Dr. Blume, and he continues not to do that. This is personal. It's improper. It's done for harassment. The arguments that Mr. Winter makes are all over the map.

How many times has he gone through the litany of testimony that he has described to you today talking about proportional rate reporting and Floxin data and what have you, when the references in the deposition transcript have nothing to do with the FDA's database, but they're about

the SCEPTRE database, and what she had asked for in discovery was the SCEPTRE database, which is what she was using throughout the course of her report initially.

She did not use the AERs database that was available publicly and which Johnson & Johnson has, has had for years. They get regularly. They analyze regularly. It is part of industry norm to have the FDA AERs database, and they have people who do this all the time. Surprise? Prejudice? Not a snowball's chance, not with Johnson & Johnson, the largest employer in the pharmaceutical industry. Not a snowball's chance that they don't have it and they don't know what is in it. They know what is in it.

So if you look at the testimony, it's about SCEPTRE, it's about AERs. Clearly she got the AERs database. Clearly she has put it aside and never used it, never reviewed it, never evaluated it, never considered it, never opined on it, never did any of those things.

If you look at pretrial order number 5, Mr. Winter conveniently latches onto the words "received" or "reviewed" and just as conveniently ignores the first part of those paragraphs which say except as provided in paragraphs 4 through 8 of the stipulation and except as provided in Rule 26, both of which talk about outside evidence and materials that you considered in your report.

These were outside. These were not considered in her report.

At the worst, at the absolute worst, she didn't think she had to produce this because of those provisions in the orders. Is it intentional withholding? That's a long way. That's a long way, especially when you start to look at the charts, and the charts in her opinion support her position.

And Mr. Winter seems perfectly capable of cross-examining those charts, as he demonstrated to you just moments ago. I don't think they have any difficulty in putting those charts up in front of Dr. Blume and asking her about proportional rate reporting ratios and whether at any given point in time they're greater than two or they're not greater than two. Mr. Winter just did that.

But more to the point on that side on the prejudice, they don't have an expert who has come forward in this case to talk about the SCEPTRE database, and the numbers that Dr. Blume did present in her initial report. They don't have anybody to testify to that. They don't have anybody who can therefore similarly testify about the AERs database and what these charts mean.

In fact, what their experts say, and this is Dr. Layde, you can't use them because they're not valid. And so if their own expert says you can't use these things,

how can they now come forward and say we're prejudiced because we can't use these things? It doesn't make sense.

So if Dr. Blume intentionally lied, which is a requirement of a showing of perjury based on clear and careful cross-examination, as the case law says, Mr. Winter didn't do a very good job of asking the questions, and he hasn't done a very good job of presenting to you today intentional misrepresentations. Not close.

But the prejudice? They have the data. They had the data for years. They now have it in the form that Mr. Altman did it. They can cross-examine it. They don't have an expert. Their expert says it's not available, and, you know, it also -- one other thing sort of in this category. Mr. Winter goes to great lengths to talk about the dates that appear in these screen shots.

The data came from Mr. Altman to me. He sent it to me, and I forwarded it along by an e-mail. You saw the e-mail. Whether Mr. Altman had done any modifications that resulted in those dates being changed, not the substance but just the memorization, those dates are what appeared on Mr. Altman's computer at the time he sent them to me.

Those dates have absolutely no bearing whatsoever on the dates they were sent or not sent to Dr. Blume, and if you will note in her affidavit, she says there was a point in time when there was a subsequent e-mailing of data

to my office. It went to my epidemiologist Darren Scherer, it did not come to me, she says, and so her office may have received it, but, A, she didn't know about it, and, B, she didn't review it.

So at the end of all of this, where do we go? At this point having done the analysis, it would be a wonderful thing from plaintiffs' perspective, if not in this case but certainly in future cases, for Dr. Blume to talk about her analysis as part of her expert report. She has submitted the supplemental report. We would like to do it here.

If we can do it here, they're perfectly in a position to cross-examine it with whatever information they have. There is nothing more that they can get. There is no additional data. If there is, they've got access to it, and if we're not allowed to use that supplemental report because that's the way it was originally framed, there is nothing they can cross-examine her about. They can't use that stuff, the charts.

If they use the charts, then they've opened up the whole issue of what her opinions are on those charts. So if they're in, they're in. If they're out, they're out for both sides. There is no prejudice on anybody's part. If you keep them out, they don't get those. They don't get to cross-examine on those charts. If you get them in, I'm

happy to have them in, and Dr. Blume can talk about them.

Now, I know that Mr. Campbell has some remarks about the personal impact of this on Dr. Blume, and Mr. Saul may or may not have a minute that he would like to address the Court as well.

THE COURT: Very well.

Mr. Campbell.

MR. CAMPBELL: Thank you, Your Honor. May it please the Court. I appreciate the opportunity to come up here in a different context. I have enjoyed the crisp weather, but obviously this is a serious issue.

THE COURT: We could have had you up here in January.

MR. CAMPBELL: You could have. I have done that route, too. It's a welcome change. In fact, I enjoyed the walk over.

If it please the Court. Let me focus strictly on this whole issue of perjury because obviously substantively we're kind of beyond my pay grade in terms of the product issues.

If I can quote from Mr. Winter's memorandum, on page 1 he writes the phrase, "Unequivocal, perjurious testimony." On page 14 he writes, quote, and reciting from another case, "Engaging in a pattern of deceit by presenting false and misleading answers and testimony under

oath in order to prevent their opponent from fairly presenting its case."

On the same page, he writes, "Ms. Blume engaged in a perjurious campaign to deny the existence of data." I think Your Honor has heard that the data we're talking about here is the AERs information. If one takes a look at the index, so to speak, in the back of Dr. Blume's deposition, you will see there is a reference in response to Mr. Winter's questioning to the AERs data 23 times, 23 times.

So the suggestion that she was denying the existence of AERs data is absolute nonsense. Mr. Winter is very careful on pages 15 and 16 to take snippets from the actual deposition in the context of the Q and A. I would like to take a few moments just to read the Q and A to give the context.

Beginning on page 11, line 24: "Question: Whose idea was it to do this type of analysis that's in the tables? Yours or Mr. Altman's?

"Answer: It was mine. If you are familiar with these type of database analysis, these are done as a matter of routine by our office. Certainly we have to do them for our FDA work, our product development clients, and we have done them for several other projects using both company databases as well as the AERs database, and we have

conducted them in the past, for example, for the Jurissac, for other products marketed by your client.

"Question: I have seen examples of proportionate rate reporting analysis. Is that the right phrase?

"Answer: Proportion, yes. Proportion rating ratios.

"Question: Proportion rating ratios, this is not what you did here, correct?

"Answer: Correct. We were -- we were not comparing in these tables" --

She is referring obviously to the report.

-- "necessarily that tendon ruptures, comparing tendon ruptures with the levofloxacin with another product. If we had been using the AERs database, we might have conducted that analysis, but our goal in this database is to look at levofloxacin.

"Your database would not necessarily have the data for your competitors' products, so in order to analyze data over time and because we had the SCEPTRE database, we focused on the levofloxacin and other reports where we have been comparing one product to another or other types of medications, we will use the AERs database and conduct PRRs.

"Question: FDA can do PRRs with respect to the fluoroquinolones, correct?

"Answer: I would imagine, yes.

"Question: Any reason to doubt that FDA has done PRRs for the fluoroquinolones?

"Answer: Yes. I don't know.

"Question: Actually some of the reports that you have done include PRRs done by regulatory bodies, correct:

"Answer: Correct. And that is one of the reasons we did not also do the AERs data in this case. We had the SCEPTRE database, and I recall the AERs data were employed in some of the citizens' petitions so we didn't duplicate efforts."

That's the complete Q and A and response and the context. If I may, Your Honor, in terms of these snippets, refer to pages 63 and 65 of the deposition. Question beginning on line 12 to give it some context:

"All right. Your understanding of a serious adverse event and separate database would have been reported to the FDA, correct?

"Answer: Serious and unlabeled would be required to FDA.

"Question: Okay.

"Answer: Serious and labeled would not necessarily have to be reported to the FDA.

"Question: Well, when you looked at the data, do you think that all the reports of tendon ruptures were sent

to FDA that Ortho-McNeil received or only a subset?

"Answer: Well, the way the 15 day reports work is serious and unlabeled. The overall annual report has to have a summarization of all serious reports.

"Question:"

Now, we get the context of these snippets.

"Okay. And all the reports," this is the question, "all the reports that go to FDA get into the Mediwatch database, correct?

"Answer: Eventually.

"Question: Yes. So when the public citizen goes into FDA's Mediwatch database, it's going to find all the reports of tendon rupture, be they the 15 day reports or annual reports subject to a lag. You know, for an annual report on X day it might be uploaded for a period of time, correct?

"Answer: Oh, let me clarify something. The AERs database accept data from everyone. It may be years until the data submitted by the company is ever downloaded AERs database, if at all. So at any point in time one has no guarantee that what's in the AERs database is a necessary reflection of what the company has said.

"The company's database is always different than the AERs database because the company receives many more reports than the FDA might receive. There have been lags

of years in which data from the company's database actually makes it into AERs because FDA has to do that. FDA does not have to do it for the report to AERs by individuals.

"Question: So in that respect, you may have more reports if there were consumers reporting tendon rupture to FDA than what the company has reported to the FDA?

"Answer: You may -- it can vary in every situation you can imagine. The AERs database is not a fingerprint of what is in the company's database.

"Question: Did you try to determine why the AERs database," and then he shifts the question midway. "Presumably public citizen knows what they are doing when they go into and look at the database?

"Answer: I would I guess -- I mean, they have submitted citizen petitions in the past. We do not independently run the AERs database. We only -- because we did have the company's database, it's considered a generally more scientific database. We rely upon the FDA or rely upon the company's. The value to AERs is that you can look at comparisons between and among products which of course you cannot do with a company's database."

That's the context of the Q and A. One of the definitions of perjury is willfully making a statement or saying a statement is true on a material matter which a witness does not believe to be true at the time of the

statement and requires actual intent. I suggest to Your Honor that the snippets that Mr. Winter has referred to in the context of her deposition doesn't come close to that when you read them in context, not even close.

I would like to go just a step further because Mr. Winter also makes another statement in this motion memoranda. He says that my client Dr. Blume stripped the disk of the AERs data. Now, he didn't make that argument this morning. I think it's because he was confronted with an affidavit and supplemental information that says he got the disk in the same fashion that was delivered to Dr. Blume by Mr. Altman, so we didn't hear that this morning, but it's in the motion, that she stripped the disk of the AERs data.

Now, the reason I'm here aside from my role as a lawyer these days, this is pretty serious. It's not just an issue of someone recklessly throwing out words in a contentious piece of litigation. This lady has testified all over the world, works primarily in assisting companies getting their products approved.

What these folks have done, what Mr. Winter has done and what the defendants have done, is made an attempt to attack her personal reputation, to discredit her in terms of the community, her personal reputation, her ability to facilitate, even assist now in perhaps getting

good drugs on the market because of this trumped up perjury business.

It's absolutely outrageous, and we have already seen the result. And when Mr. Dames and I spoke some weeks ago, I said, look, we need to take care of this now because it's going to impact the future cases that she is participating in, and sure enough we have a case in Arkansas.

I think it's attached to the papers that Mr. Goldser has filed, where there was a motion in limine to address Mr. Winter's motion and memorandum, which the Court granted. In other words, all this stuff was excluded in the case, and she was allowed to testify.

Mr. Winter talks about parsing. What he has parsed is received or reviewed, and he has focused on received because she got, some e-mail was sent to her that contained AERs data from Mr. Altman, he has parlayed that into, she discarded it, she considered it, she reviewed it, she looked at I think was his phrase, considered and disregarded it.

She never considered it. Never considered it, and in her sworn deposition testimony, questions that he asked, she identified what she considered, and in her report, supplemental report and affidavit, she said I didn't consider it, and then I asked a very obvious

question. I suppose it goes to the prejudiced argument. I don't mean to get involved in that argument.

But what lawyer in cross-examining an expert would ask questions about information that an expert didn't rely upon or consider in formulating their opinion? You wouldn't even delve into that. You wouldn't even open that door. But guess what? They now have opened that door. I hope there is an opportunity to walk through it with the AERs data.

Thank you, Your Honor. I would respectfully ask the Court to rule on this issue fairly quickly because it does have a significant impact on her. Thank you, Your Honor.

THE COURT: Thank you, Mr. Campbell.

Mr. Saul? Sure.

MR. SAUL: Your Honor, if you'll recall the defendants' expert in this case, the epidemiologist is Dr. Layde. Dr. Layde issued his report on November 6th, 2009, and I'm quoting directly from the report, Dr. Layde says in part, "Therefore, AERs cannot be used to calculate the incidence of an adverse event in the U. S. population."

Dr. Layde says that the database essentially is irrelevant, their own expert. A year later -- Mr. Dames wouldn't do this. He wouldn't file such a motion. He had to sign it because he works for the company.

Ms. Van Steenburgh wouldn't sign such a motion, nor would Mr. Robinson.

They hired essentially Mr. Winter to come in here and attack Ms. Blume, Dr. Blume, personally. It goes beyond the pale of any civility in the courtroom. It's specifically to get Dr. Blume to not be able to testify for plaintiffs, which she does on a reasonably regular basis, and they're after her.

They're in this courtroom through Attorney Winter in order to discredit her. I ask that, I for plaintiffs, ask that this be stricken from the record, the entire motion be sealed because they're just trying to attack her reputation and keep her from working in the industry from here going forward.

Thank you.

THE COURT: Mr. Dames?

MR. DAMES: I apologize. I just want to say a couple of words. I just want to respond to that last statement by Mr. Saul. This motion would not have been filed if I believed it was inappropriate. It's filed based upon my own agreement and belief that it was appropriate for the Court to hear and in fact to grant the relief that we request.

I'm sure I speak for the other, for the co-counsel, and I don't need, Mr. Winter doesn't need my

validation, but he is going to get it anyway. I believe the analysis and the argument and the statements are exceptionally meritorious in my own opinion or else we would never have had the Court hear it.

THE COURT: Mr. Winter?

MR. WINTER: Your Honor, I just put up a slide that I showed you 15 or 20 minutes ago, and we were accused of giving you only a snippet. My learned colleague chose to read that entire answer to you presuming that I had only read you a snippet.

The fact is, that's the entire answer, and what I now understand is, there were 23 questions. They said 23 references. I'm assuming 23 questions about the AERs database. Did you hear someone say to you in response to any of those questions 23 times, I looked at AERs. I had Mr. Altman run it, but I discarded it?

In other words, 23 times she had the chance to tell the truth, so this is not one question out of context. It's a little flabbergasting for someone to say I didn't do something intentionally when they did it 23 times.

Now, you were told that somehow the information that Mr. Goldser isn't probative. I made copies of the screen shots. There are four of them. They're a little bit easier to read, but the AERs database, Judge, they're all, the modified date, and we all know how this works,

modified on March 23, 2010.

So the notion that this was discarded six months earlier can't be true. You have two pages from November 6th and two pages from March 23, Judge. One page is SCEPTRE. One page is AERs, and it's consistent.

So if the explanation now is, well, it didn't go to Ms. Blume. It went to someone on her staff, which is what was suggested to you, then that definition of "we" makes no sense because allegedly "we" meant her organization, and I'm not focusing on that word to be snide. That's her defense.

Now, someone brought up the motion in the *Prempro* litigation. Your Honor should be well aware that that motion was not filed by any defendant, nor has any lawyer on this side of the table ever contacted anyone about this motion. You want affidavits, declarations from any lawyer on the defendants' side. We haven't said a word to anyone about this.

Plaintiffs' lawyers go want to make a motion, that's their prerogative, so the suggestion that we somehow started a forest fire here is just not correct. Yes, everyone knows about AERs, but the question is, did you as an expert consider it, did you use it. Now the notion that Mr. Altman sent her this data and she says I didn't use it, okay. But she clearly said I looked at it and I didn't

consider it worthy for including in my report. I am paraphrasing paragraph 13 of her affidavit.

She had to look at it. So we're not parsing on the word "received." It's very obvious what happened here, and I'm not going to go back to the prejudice, but it's abundantly clear here what happened. And finally on this stripping of the data, Judge, we didn't get it. I mean that's abundantly obvious.

You now know that Ms. Blume had it as of March 23, 2010, and Mr. Altman said, and we gave you this, he did the disk that was produced at Ms. Blume's deposition, and he didn't include the AERs database. No one is disputing that, and it's undisputed who gives directions to Mr. Altman.

So the conclusion that we suggested to you that she ordered it to be stripped is one that you have to take because it's undisputed fact, and, you know, I don't think anyone on this side, if we make an argument to you in our papers which is undisputably correct, I'm not going to get up here and waste your time and say, Judge, I gave you the affidavit and I gave you the deposition cites. That's like uncontroverted.

So the fact that we didn't bring it to your attention doesn't mean we don't believe it to be 100 percent true. Your Honor, these are very serious matters,

and the notion that I was hired to come in here and do this? I have been working on this case, what, two and a half years? We all have roles to play here, but I don't engage in name calling, Judge, but that was just completely false.

Thank you, Your Honor.

THE COURT: Thank you, Mr. Winter.

Anything else?

MR. GOLDSER: No, Your Honor, not on this motion.

THE COURT: Very well. We have got about 15, 17 minutes left. What do you want to do on the other two motions? I have read all the materials and understand it.

MR. GOLDSER: I can address Waymack in 90 seconds.

THE COURT: Go ahead. I also was able to read the, is it, *Trasylol*?

MR. GOLDSER: Your Honor, my argument would have been a Power Point. I have presented it to you. Consider the argument as if made by my Power Point. It's very simple. Dr. Waymack has now a long-standing history of offering opinions that are contrary to law. We saw it first in *Gadolinium*. We saw it in the *Robinson versus McNeil* case where I think it was Mr. Dames's firm represented Ortho-McNeil in that case.

We now have *Trasylol*. He has done it here again.

My Power Point lays out bullet point by bullet point what he said versus why it is contrary to law. Consider the argument, if you would be so kind, as made based on my Power Point. Of course, we have the *Trasylol* decision. He did it again.

THE COURT: Mr. Winter?

MR. WINTER: Yes, Your Honor. May I proceed, Your Honor?

THE COURT: You may.

MR. WINTER: Your Honor, you do have all the papers, and I think it's important for you to see that in different regulatory situations there are obviously different FDA rules and procedures that apply, and the *Robinson* case is a very good example because the Seventh Circuit issued an opinion, and after the plaintiffs had filed their opposition to you where the Seventh Circuit said Dr. Waymack's opinion about whether or not labeling could have been changed under those specific circumstances of that case with that medicine was correct.

And the *Trasylol* case is another example, and in the *Trasylol* case, the plaintiffs' expert has already been excluded, and you actually have references to that expert's exclusion, Dr. Parisenne, and the judge made rulings. The judge said you can't give a regulatory chronology, which is an issue on both sides for experts. You can't testify

about corporate intent, and that means you can't testify about the intent of FDA in doing something.

We quite frankly agree with that, Your Honor, and have not proffered Dr. Waymack to do that. I mean, you have issues relating to class labeling, which is not in every case. You have issues relating to the FDA's clear rules, and both sides have cited them to you, on how you put comparative data in a package insert.

And FDA has an express rule on that, and it has a waiver provision to it, and there is a lot of expertise involved with how that provision works. Comparative data, again, Judge, is a core issue here. That issue has not been addressed in any of these opinions. So that is a very appropriate area for someone who worked for years at FDA, acknowledged epidemiologist, acknowledged physician, can explain what happens there, which is what we would offer him for.

THE COURT: Well, the problem with these series of opinions involving Mr. Waymack is that courts keep saying he is testifying contrary to law. *Trasylol* says the same thing. I mean --

MR. WINTER: Judge, you are right on certain areas, and those certain areas are not areas that he would be giving an opinion on which is why I said to you, *Robinson* said that Waymack was right in that area, and just

so the issue from these other courts is, can you make that change being effected CBE, labeling change without prior approval, which is what the *Levine* case was, and courts have said, this is what *Levine* says, so you can't say that a company can't do a CBE.

Judge, we would never say, nor did Dr. Waymack say here, that a company can't do a CBE in certain circumstances because, Judge, we did one for Levaquin in 2001. We went to FDA and said we want to change the warning for Levaquin to add a statement about risks of tendon rupture in elderly patients taking steroids. It went in in December of 2001. That's in Dr. Waymack's opinion that that was done and proper.

There are other issues about other conduct where he has opinions that are consistent with FDA regulations. So the notion that Dr. Waymack would be testifying contrary to law in this case is just not accurate and, Judge, we could never say to you, you can't do a CBE on your product alone for an issue relating to your product because we did it.

So, you know, if you look at that latest *Trasylol* opinion, the areas that Dr. Waymack is permitted to testify are ones that fall squarely within areas that he wants to testify here, same with the *Gadolinium*, because *Gadolinium* on reconsideration, the judge said Dr. Waymack can testify.

I mean, you're right. If there was not the judge reversing himself, for want of a better term, I would say the argument has a little bit more traction, but the fact is, there are areas that Dr. Waymack clearly can provide opinions on. He is not going to come in and say I disagree with *Wyeth*.

THE COURT: What about labeling obligations?

MR. WINTER: Pardon me?

THE COURT: What about labeling obligations?

MR. WINTER: Well, I think his opinions as he expressed them in his report and his deposition here are consistent with the law. He said, he acknowledged that a company has -- I'm paraphrasing the word -- significant labeling obligations and that there clearly is a partnership with FDA and, you know, just to go to the initial labeling, the original labeling that gets approved, there are FDA requirements, and every court has acknowledged that at that stage there is a lot of FDA responsibility.

So he clearly can testify about that, and *Trasylol* says he can testify about that. So you have to look at things on a continuum, and when you get to the post marketing situation and the question of can you do a black box sooner, I mean, that's an issue, Judge, that I think the other side says they're not going to have someone offer

that opinion because that clearly contradicts the regulations, and actually it's common ground, to use a word of the experts. You can't do that.

So -- and that issue is specific to a case and would be one that if, you know, you allowed someone to testify, we would clearly need Dr. Waymack to respond to that. I mean, if you say you can't argue that a black box should have been sooner, plaintiff, I think you can rest assured, Your Honor, on our side we wouldn't have Dr. Waymack say the judge is right.

I think the papers do lay out the arguments, Judge, and I think his proposed opinions here are consistent with what courts have said after *Wyeth* he can give opinions on, particularly on those issues of comparative labeling, and to the extent we're going to have to talk about black box sooner and we're going to talk about the launch approval and we're going to talk about interactions between, you know, different regulatory bodies.

I mean that's clearly appropriate areas, but he is not going to come in here with an opinion that contradicts law, nor would he ever give a legal opinion. He knows that's improper. Thank you, Your Honor.

THE COURT: Mr. Goldser?

MR. GOLDSER: I think I'm in a different universe

from Mr. Winter because that's not the way Dr. Waymack testified. First he said, paragraphs 1 through 59, I think those are the numbers in his report, are the same and have been the same for the last five years, and those are the opinions that were thrown out in *Gadolinium* and *Robinson* and now *Trasylol*.

So his opinions have not changed despite the fact that he has been thrown out, but more specific than that, in the brief and in this Power Point I have highlighted for you specific opinions. He says only some serious adverse reactions must be included in the label. That contradicts 21 C.F.R. 201.57(e).

He says, the class label can be changed only if they are randomized clinical trials. That didn't happen. It happened in other ways, in Floxin of all drugs, where there is a label that is a nonclass label for Floxin about insomnia. Changes being effected may be used only if new data, quote, "Convincingly contradicts," end quote, the existing label. That contradicts 201.57(e).

J & J has minimal discretion as it relates to the content of the label. That violates the same regulation. Only evidence of causation is sufficient to warrant a change. That is not anywhere close to be true, and association without causation is allowable to change a label. Minor changes can be made without approval in an

annual report but do not affect the safety of the drug. Oh, that is so far wrong, 21 C.F.R. 314.70. That's the whole CBE regulation.

I mean, it goes on and on and on, and if you have got a litany like that, together with his testimony that violates *Wyeth*, what is left? And if he's allowed to talk about any of this stuff with all of these contradictory or contrary to law statements, his overall testimony is tainted. He is a nonstarter.

MR. WINTER: Just, Judge, in the reply that we submitted to you on Dr. Waymack, we gave you all of the references that explain why what Mr. Goldser just told you was something either not in context or if you looked at the third answer that followed the third question, you clearly understood what he was addressing, so I'm not going to go back there.

I think if you look at the papers, Judge, you will see that, you know, Mr. Goldser just told you about how he wants to cross-examine Dr. Waymack on certain points, and that's not what *Daubert* is about. Thank you, Your Honor.

THE COURT: Thank you, Mr. Winter. Okay. We just have a few minutes. Any points on the other aspect of the Blume motion that the Court should consider? Again, I have extensive briefing.

MR. WINTER: You have extensive briefing, Judge, and let me just hit a couple of high points. This foreign regulatory testimony, I mean, we have cited to you both in the Dr. Blume motion and in our in limine motion, I think there are five or six courts which have said you can't give this type of testimony, and one of them applies to Ms. Blume, the *Viagra* case. It's just not *Viagra*. It's *Baycol*, it's the Sixth Circuit's decision in *Meridia*, and we have cited the other, *Seroquel*.

The same applies to trying to be the regulatory historian, and I know you have that corporate intent motion, but she is, you know, she wants to give what our intent and motive was in doing things, and that's not proper. We cited to you the *Prempro* decision from the Eighth Circuit where a result got reversed by the Eighth Circuit and sent back because the plaintiffs had used someone like Ms. Blume, and I'm not pejorative, to go and just -- I looked at this document and it means this.

That clearly is invading the function of the jury to understand that. Now, on the database issue, the table that was in her report, as I said we cited I think 15 cases to you that you can't use that, and we have cited cases where other courts have in fact excluded that precise analysis.

And what I want to just point out to Your Honor

is that there are steps in pharmacovigilance. What they have identified is step one, looking at numbers. There is a step two, a step three, a step four. So they stopped at step one. They counted numbers, and the *McLean* case from the Eleventh Circuit which we have cited to you is a very clear example of that expert in that case stopped at step one, and the Court said, no, you need to do the complete methodology here, and that didn't happen here.

So I think if you take those components out, if she wants to say we have a duty to warn patients directly, I don't think that's the law in Minnesota. She wants to have opinions about preclinical and toxicology, but then she says, but I'm not an expert in that. I leave it to others.

We have given you a lot of paper there, Judge, but when you go through these various topics, each of them, there is a long line of cases that say you can't do that, some of them specific to Ms. Blume, some of them to witnesses just like Ms. Blume. I mean, that PRR analysis, we have cited the cases. You can't use that, so that, you know, is separate and apart obviously from the conduct.

And to come in and say Dr. Beecher would have done something different, the prescriber in Schedin, she didn't look at any of those records. She's not a doctor, so how can she give those type of opinions. And then when

on the labeling and warning, as best we can determine, she says we should have done a dear doctor letter after the 2001 label change. Well, the facts, Judge, and you have them, is we had changed our labeling in 2004, and the prescribing physician has testified he was aware of that.

So you get a question of, how does her testimony fit the case? If she wants to talk about a dear doctor letter for labeling that was later revised and the prescriber knows about it, where is that opinion probative? So I know at the end I know we have extensively briefed this, but I think if you follow what we have laid out is the areas of her testimony, they all fail. Thank you, Judge.

THE COURT: Thank you, Mr. Winter.

Mr. Goldser?

MR. GOLDSER: Your Honor, I would like to talk about one subject only, and that is the foreign regulatory issue. It has to do with how the foreign regulatory material bears on this litigation and its relationship to the United States.

Dr. Blume is an expert on U. S. regulatory information, and the issue that exists here -- gosh, I hope I have the right one. Yeah, that's the right one. One second, if you'll indulge me. There we go.

The issue is how what was going on in Europe has

any bearing on the American regulatory and marketing status of Levaquin. Dr. Blume talks extensively about that. She talks about what was going on in Europe as a factual predicate, and then in her report she says how does that affect the American market, how does that affect the American regulatory system. That's the regulatory context, which is the phrase that was used in *Trasylol*.

So she is entitled to talk about all of the things in a regulatory context, and you know, if she doesn't talk about the documents at all, then she has no foundation for her opinion, and I'm going to get that objection from the defense.

So there is a scope of testimony that she is allowed to give about these documents, so long as she talks about them in regulatory context, and I want to give you that regulatory context. This is Dr. Kahn. You have heard so much about Dr. Kahn, and he is talking about what is going on in Europe. This is what he has to say about the regulatory context in Europe:

(Videotape played as follows:)

"Dr. Kahn: Let me give you an example. Suppose the French regulatory authority said, we see a signal. This drug is dangerous. We disregard the hundreds of millions of other prescriptions in the safety database and don't share the signal. We are going to re-label the drug

in France and Belgium or any European bailiwick as being too toxic to use except in situations where the organism is proven to be resistant to everything but levofloxacin.

"Well, that label would have stayed in Europe for one nanosecond before it was communicated around the world. Other regulatory agencies would have probably been afraid not to take the same stand, and suddenly the best quinolone available would be taken off the market, virtually taken off the market.

"This is, in fact, what happened to sparfloxacin. When the FDA said it can only be used in situations A, B and C, which can be counted on the fingers of one hand, the drug essentially went out of existence."

MR. GOLDSER: You can see pretty clearly that what was going on in Europe in Dr. Kahn's own mind, the guy who was in charge of the molecule, was going to have a significant bearing on U. S. regulatory status. Dr. Blume can talk about that because she is an expert in the U. S. regulatory status.

I mean, there are multiple additional documents about action of European regulators is likely to trigger an FDA inquiry. I mean, it goes on and on and on. That's the kind of stuff that she is going to talk about in terms of foreign regulatory. That's why she is allowed to do it. Thank you.

THE COURT: Mr. Winter, did you have something else?

MR. WINTER: Very briefly, Your Honor. If they want to cross-examine Dr. Kahn, they can cross-examine Dr. Kahn. We cited to you Ms. Blume's testimony where she said she didn't review any of these foreign regulatory files herself. It's at page 109 of her deposition.

So there is a foundational issue, put that aside, but the reality is, when you look at every judge who has looked at the ability of someone to testify about foreign regulatory matters, they're uniformly excluded, and there are a lot of reasons set forth as to why that happens, and this case is no different.

Thank you, Your Honor.

THE COURT: Thank you, Mr. Winter. Thank you, Counsel. I appreciate your coming in early this morning. The Court will take the motions under advisement and will issue a written order quickly.

MR. GOLDSER: Thank you, Your Honor.

MS. VAN STEENBURGH: Your Honor, one other housekeeping matter. I had mentioned to Holly that we are going to bring a motion to quash two trial subpoenas, and she suggested I bring it up with you. That might be something you want to hear on the 3rd of November at the pretrial conference. If that's true, that's the date I

will put in my notice.

THE COURT: Okay. Do you have it filed yet or not, the motion?

MS. VAN STEENBURGH: No, because we didn't have a date. We're ready to file today.

THE COURT: Okay. That's fine. Let's presume it will be on the 3rd unless the plaintiffs have a difficulty with that.

MR. GOLDSER: And we will do the same with any discovery motions that we have for the 3rd. Thank you, Your Honor.

THE COURT: We will be in recess.

THE CLERK: All rise.

* * *

I, Kristine Mousseau, certify that the foregoing is a correct transcript from the record of proceedings in the above-entitled matter.

Certified by: s/ Kristine Mousseau, CRR-RPR
Kristine Mousseau, CRR-RPR